

Remarks

Claims 62-95 are pending in the subject application. Applicant acknowledges that claims 82-95 have been withdrawn from further consideration as being drawn to a non-elected invention. By this Amendment, Applicant has canceled claims 62-95 and added new claims 96-132. Support for the new claims can be found throughout the subject specification and in the claims as originally filed (see, for example, page 4, lines 5-15, page 11, lines 10-22, page 13, line 6 through line 24, page 14, line 4-line 25, and pages 81-83 (Example XLIX)). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 96-132 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Claims 62-81 are rejected under 35 US §112, first paragraph, as failing to comply with the written description requirement. The Office Action argues that claims 62-67 recite “reducing the pathogenicity” and that no support for such a limitation was found in the specification. Applicant respectfully submits that this issue is moot in view of the amendment and cancellation of the claims. The Office Action also argues that the use of super critical or critical liquid nitrogen is not supported. Accordingly, reconsideration and withdrawal of the rejection under 35 US §112, first paragraph, is respectfully requested.

Claims 62-81 are rejected under 35 US §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Again, it is respectfully submitted that the rejection is moot in view of the cancellation of the claims. Accordingly, reconsideration and withdrawal of the rejection under 35 US §112, second paragraph, is respectfully requested.

Claim 62 was rejected under 35 US §102(b) as being anticipated by applicant’s admissions (specification, page 8-9). Claims 62-70, 73-74, 76 and 80 were rejected under 35 US §102(b) as being anticipated by Tallafus (U.S. Patent No. 5,193,350). Claims 62-70 and 76-81 were rejected under 35 US §102(b) as being anticipated by Davis *et al.* (U.S. Patent No. 4,848,094). Claims 62-72, 76, and 80-81 were rejected under 35 US §102(b) as being anticipated by Kawashima (JP Patent No. 358210023). The Office Action argues that the previously presented claims are anticipated by the cited references and that it is inherent that the patented process will obtain the claimed attributes of the final products. The Office Action also indicates that the burden has been shifted to Applicant in

order to demonstrate patentable differences between the products produced in the prior art and those produced by the claimed methods (citing to *In re Best*). Applicant respectfully traverses.

Applicant respectfully submits that no such demonstration is required in the instant application. As the Patent Office has indicated, the claims under examination are directed to methods of reducing the allergenicity of foods containing allergens, such as nuts, milk, or egg or the allergenicity of vaccine components, including those containing eggs products. No product claims are present in the instant application and, indeed, such product claims were restricted away in the Office Action of September 18, 2002. Accordingly, it is respectfully submitted that the burden of demonstrating patentable differences between the products of the prior art and those of this invention has not been shifted since such product claims do not exist in the subject application.

Turning to the issue of anticipation set forth in the Office Action and as the Patent Office is aware, anticipation (under the doctrine of inherency) is to be distinguished from accidental or unwitting anticipation. For example, the accidental attainment of a claimed invention without recognition of the result or how it was achieved has been held to not constitute anticipation (*see Tilghman v. Proctor*, 102 U.S. 707, 26 L.Ed. 279 (1880)). In this decision, the Supreme Court ruled that anticipation could not be found where the prior art process was not directed to the process claims at issue and because the product produced by the method was accidentally and unwittingly produced, without knowledge of what was done or how it was done. In *Eibel Process Co. v. Minnesota & Ont. Paper Co.*, 261 U.S. 45 (1923), the Supreme Court also held that accidental results, unintentional and unappreciated, did not constitute anticipation. Other decisions indicate that cases applying this doctrine have consistently held that what is required is true fortuitousness, as in the example of a chemical being produced as a side effect to no one's knowledge (*see Clements Industries Inc. v. A. Meyers & Sons Corp.*, 12 USPQ2d 1874, 1879 (DC SNY 1989) citing *Tilghman v. Proctor*, 102 U.S. 707 (1881)). Additionally, if a claimed method comprises steps identical to those of a method practiced in the prior art, and the same result would have been achieved in the prior art method, the accidental or unwitting achievement of that result cannot constitute anticipation (*see In re Marshall*, 578 F.2d 301, 198 USPQ 344 (CCPA 1978); *see also In re Felton*, 484 F.2d 495, 500, 179 USPQ 295, 298 (CCPA 1973) (accidental or unwitting duplication of an invention cannot constitute an anticipation.)). Furthermore, an anticipating reference must describe the patented

subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention. See *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990); *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 1566, 1567, 7 USPQ2d 1315, 1317 (Fed. Cir. 1988).

Applying these concepts to the presently claimed invention, it is clear that the cited references fail to describe the claimed subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized or appreciated by persons of ordinary skill in the field of the invention. Indeed, the cited prior art methods are devoid of any teaching that the allergenicity of allergens can be reduced via treatment with super critical fluids or critical liquid gases. Each of the references fails to appreciate that the products produced by the processes had reduced allergenicity. Accordingly, reconsideration and withdrawal of the rejection under 35 US §102(b) is respectfully requested.

Claim 73 was rejected under 35 US §103(a) as being unpatentable over Davis (U.S. Patent No. 4,848,094). The Office Action argues that it would have been obvious to subject defatted milk to the process of Davis *et al.* because the production of defatted milk was notoriously well-known and that legal precedent renders the claimed invention obvious as the courts have taken the position that treating known ingredients in ways that differ from the former practice does not rise to the level of invention. Applicant respectfully traverses.

All the claim limitations must be taught or suggested by the prior art to establish the *prima facie* obviousness of a claimed invention. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). As indicated above, Davis *et al.* fails to teach methods of reducing the allergenicity of milk products; rather, Davis is directed to the freezing of food droplets. The legal precedent cited in support of the obviousness rejection fails to remedy this defect in the primary reference and, thus, it is respectfully submitted that a *prima facie* case of obviousness has not been established for the subject invention.

However, assuming, *arguendo*, that a *prima facie* case of obviousness has been raised, it is respectfully submitted that it is unexpected that the allergenicity of milk can be reduced as provided by the subject invention. For example, treatment of non-fat milk in liquid nitrogen according to the subject invention reduces its allergenicity to about the levels observed as “Background Binding” in ELISA assays of using allergic serum (see page 82 and Example XLIX (49) at pages 81-83). Such a

reduction of allergenicity would be unexpected by one skilled in the art in view of the teachings of the cited reference. Accordingly, reconsideration and withdrawal of the rejection under 35 US §103(a) is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicant's agreement with or acquiescence in the Examiner's position. Applicant expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: 2421 N.W. 41st Street, Suite A-1
Gainesville, FL 32606-6669

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